K080425
R1/2

5. 510(K) SUMMARY

APR 23 2008

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Rd. Diamond Bar, CA 91765 USA Phone: 800-729-7272 Fax: 909-839-8804
Date:	February 13, 2008
Contact Person:	Balaka Das Specialist, Regulatory Affairs
Proprietary Device Name:	CS REFSTAR Catheter
Common Device Name:	Electrophysiology Mapping Catheter
Classification Name:	Electrode Recording Catheter (per 21 CFR 870.1220, Product Code DRF)
Predicate Device:	1. NAVISTAR diagnostic catheter (K954390) 2. WEBSTER fixed curve catheter D-1086-566 (K841802)
Manufacturing Facilities:	Biosense Webster, Inc. 15715 Arrow Highway Irwindale, CA 91706 USA

5.1 Substantially Equivalent To:

The Biosense Webster CS REFSTAR is substantially equivalent to the Biosense Webster NAVISTAR diagnostic catheter (K954390) and the WEBSTER fixed curve catheter D-1086-566 (K841802).

5.2 Description of the Device Subject to Premarket Notification:

The Biosense Webster CS REFSTAR Catheter has been designed to be used with the CARTO 3 EP Navigation System (a magnetic field location technology) to facilitate electrophysiological mapping of the heart.

The CS REFSTAR Catheters have a high-torque 7 Fr shaft with a deflectable tip section containing an array of ten platinum/iridium electrodes that can be used for stimulation and recording of cardiac electrical signals. In addition, there is a single eleventh electrode located on the shaft. This Porterfield type electrode is designed to be positioned in the Vena Cava during use where it will perform as a reference unipolar electrode. The catheter has a location sensor embedded in the tip section that transmits location information to the CARTO 3 EP Navigation System. The shaft has a working length of 115 cm.

The CS REFSTAR Catheter tip deflection is controlled by a proximal hand piece that features a thumb operated sliding piston and is offered in two curve types, D and F. The plane of the curved tip can be rotated during use.

The CS REFSTAR Catheter interfaces with standard recording equipment and the CARTO 3 EP Navigation System via interface cables with the appropriate connectors.

5.3 Indications for Use:

The CS REFSTAR Catheter is indicated for electrophysiological mapping of cardiac structures ie., recording and stimulation, including the Coronary Sinus. In addition the CS REFSTAR Catheters are used with compatible CARTO EP Navigation Systems to provide catheter tip location information.

5.4 Performance Data:

The CS REFSTAR Catheter underwent extensive bench (mechanical, electrical and simulated use) testing. The catheter passed all testing in accordance with appropriate test criteria and standards. The catheter was also subjected to animal testing which demonstrated that the catheter was safe for use in the coronary sinus and that it is capable of functioning within the CARTO 3 EP Navigation System.

5.5 Overall Performance Conclusions:

Based on the results of risk analysis, bench, and animal and studies performed it is concluded that the CS REFSTAR described in this submission is as safe and effective as the predicate devices for its indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

Biosense Webster
c/o Ms. Balaka Das
Regulatory Affairs Specialist
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765

Re: K080425
Trade/Device Name: CS RefStar Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: February 13, 2008
Received: February 15, 2008

Dear Ms. Das:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) No (if known): _____

Device Name: CS REFSTAR Catheter

Indications for Use:

The CS REFSTAR Catheter is indicated for electrophysiological mapping of cardiac structures ie., recording and stimulation, including the Coronary Sinus. In addition the CS REFSTAR Catheters are used with compatible CARTO EP Navigation Systems to provide catheter tip location information.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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B Zimmerman

ision Sign-Off)
vision of Cardiovascular Devices
(k) Number K080425